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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/321,179	10/11/1994	WALTER P. CARNEY	40441CZIPWNP	1590

7590 12/30/2003

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EXAMINER

HOLLERAN, ANNE L

ART UNIT	PAPER NUMBER
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1642

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DATE MAILED: 12/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

08/321,179

Applicant(s)

CARNEY ET AL.

Examiner

Anne Holleran

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 May 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

1. Since this application is eligible for the transitional procedure of 37 CFR 1.129(a), and the fee set forth in 37 CFR 1.17(r) has been timely paid, the finality of the previous Office action is hereby withdrawn pursuant to 37 CFR 1.129(a). Applicant's submission after final filed on May 2, 2003 has been entered.

2. Claim 19 is pending and examined on the merits.

Claim Rejections Withdrawn:

3. The rejections to claim 1 are withdrawn in view of the cancellation of claim 1.

New Grounds of Rejection:

4. Claim 19 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 19 is indefinite because it contains the phrase "said product", which lacks antecedent basis in the claim.

5. Claim 19 is rejected under 35 U.S.C. 102(e) as being anticipated by Hudziak (US Patent 6,015,567) or Ring (US Patent 6,054,561).

Claim 19 is drawn to a substantially purified extracellular domain of the human neu gene product that is detectable in a biological fluid by monoclonal antibody OD-3, NB-3 or TA-1. The detectability of the extracellular domain of the human neu gene product, or of the entire human neu gene product, by any of these monoclonal antibodies is considered to be an inherent property of the extracellular domain of the human neu gene product. Because the claim lacks a transitional phrase and also because of the lack of antecedent basis for "said product", the claim reads on a polypeptide that is either the extracellular domain of, or the entire human neu gene product.

Hudziak teaches a polypeptide that is the extracellular domain of a neu related gene product and that has a molecular weight from about 95,000 daltons to about 115,000 daltons (see for example, column 1, lines 15-20, column 6, line 55-column 7, line 6, and figure 12 (including description)). Ring teaches a composition comprising the human neu related protein that comprises the extracellular domain of a neu related gene product and which has a molecular weight from about 95,000 daltons to about 115,000 daltons (see for example, abstract, column 5, lines 24-40, and column 27, lines 1-40). Therefore, Hudziak or Ring teaches the claimed invention.

6. Claim 19 is rejected under 35 U.S.C. 102(b) as being anticipated by either Yamamoto (Nature, 319: 230-234, 1986; cited in an IDS) or Coussens (Science, 230: 1132-1139, 1985; cited in an IDS).

Yamamoto teaches the human c-erb-B2 polypeptide and teaches the extracellular domain (see abstract, page 233, fig. 4, and page 233, 1st col.). Coussens teaches the human neu gene

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product (Figure 1), and teaches the extracellular domain (page 1133, 2nd to 3rd col.) Therefore, either Yamamoto or Coussens teaches the claimed invention.

Conclusion


No claim is allowed.

Any inquiry concerning this communication or earlier communications from the Office should be directed to Anne Holleran, Ph.D. whose telephone number is (703) 308-8892. Examiner Holleran can normally be reached Monday through Friday, 9:30 am to 2:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D. can be reached at (703) 308-3995.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist at telephone number (703) 308-0196.

Anne L. Holleran
Patent Examiner
December 27, 2003


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